AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to FIGS. 19 and 24 to overcome objections in the Non-Final Office Action mailed July 23, 2007.

REMARKS

Claims 1 – 23, 32 – 51, 53 – 58, 62 – 70, 73, 84 – 86, and 95 – 99 are pending in this application. Claims 8 – 12, 16, 17, 33, 35, and 36 have been withdrawn in the response filed on June 14, 2007.

In a Non-Final Office Action mailed July 23, 2007, the Examiner additionally withdrew claims 13, 40 – 45, 51, 53 – 58, 62 – 70, 73, 86, 95, and 97 – 99 as being drawn to a non-elected species, there being no allowable generic or linking claim.

Additionally, the drawings have been objected to as failing to comply with 37 CFR 1.84(p)(5) because they include reference characters not mentioned in the description. The specification and drawings have been amended to overcome this objection.

Claims 18 – 23 have been rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claims 1 and 18 have been amended to make clear that it is the progeny phage that is dissociataed. It is believed this overcomes the objection.

Claims 37 – 39, 46 – 50, 84, and 85 have been rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. These claims have been amended to overcome this rejection.

Claims 43 – 48 and 50 have been rejected under 35 USC 102(b) as being anticipated by Takahashi et al. (WO 90/08944 – the specification of which is translated in US Patent No. 6,322,783 – hereinafter "Takahashi et al."). This rejection is respectfully traversed. Claims 43 – 45 have been withdrawn, and Takashi et al. does not seem to relate to them, so it is assumed that the Office Action meant to reject claims 46 – 48 and 50. Claim 49 has been incorporated into claim 46; therefore, this rejection is overcome.

Claim 49 has been rejected under 35 USC 103(a) as being unpatentable over Takahashi et al in view of Mouton et al. (US Patent No. 5,789,174, hereinafter "Mouton et al."). This rejection is respectfully traversed. If Mouton et al. were combined with Takahashi et al., what is obtained is a process in which bacteriophage closely related to the parent bacteriophage are combined with the sample and it is determined if there is a result. This does not have anything to do with the claim, which claims providing a reference indicating an assay result if no target microorganisms are present in said sample. This is nowhere suggested or disclosed in Mouton et al.; thus, the amended claim 46 is patentable.

Claims 1 – 3, 6, 14, 15, 18 – 23, 32, and 96 have been rejected under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over, Rees et al. (WO 92/02633, hereinafter "Rees et al."). This rejection is respectfully traversed. The claims state that it is the amount of parent bacteriophage that is below the detection limit. The Office Action states that, since Rees et al. discloses that the amount of progeny phage that may be below the detection limit and are allowed to multiply to become above the detection limit, it would be obvious to do the same with the parent. This improperly reads the present invention into Rees et al. Rees et al. teaches that the parent phage are destroyed. The MPEP requires that the whole of the reference be considered. Rees is one skilled in the art. Clearly, it did not occur to Rees that he did not have to kill or destroy the parent phage; all he had to do was put in an amount that was below the detection limit. If Rees did not realize this at the time of his disclosure, one skilled in the art would not have recognized it. The invention has the distinct advantage that, if any phage is detected, it must be progeny phage. It is much simpler and also avoids the contamination of the sample with bacteriophage debris that can interfere with the assay. It is only the present application that has realized that, if the amount of parent bacteriophage is below the detection limit, there is no need for removing or destroying the parent bacteriophage. The Office Action is using the hindsight of the present invention to put into Rees et al. what is not there. In addition, claims 18 – 23 as amended are patentable because Rees et al. does not teach dissociating the progeny bacteriophage.

Claims 4, 5, 7, 37 – 39, 84, and 85 have been rejected under 35 USC 103(a) as being unpatentable over Rees et al. as applied against claims 1 – 3, 6, 14, 15, 18 – 23, 32, and 96 above, and further in view of Rittenburg et al. (US Patent No, 5,710,005, hereinafter "Rittenburg et al."). This rejection is respectfully traversed. As indicted above, Rees et al. does not teach the limitation of using an amount of parent bacteriophage below the detection limit, and, in fact, teaches that the parent bacteriophage should be removed or destroyed, which is not necessary if the amount was below the detection limit. Further, if Rittenburg et al. were combined with Rees et al., what one would get at most is a method of detecting a gradient in a bacteriophage concentration. There is nothing to suggest that bacteriophage would even flow in a flow strip. All Rees et al. teaches is the use of an immunoassay, which, as read by the Examiner, means an antibody is used. There are hundreds of assays using antibodies, and nothing in Rees et al. suggests a flow strip may be particularly effective. Further, while an antibody is used in a flow strip, a flow strip is much more complex than just using an antibody, and use of an antibody does not teach all the other complexities of a flow strip. Moreover, nothing in the combination of references teaches the use of a colored bead or a colored anything in connection with bacteriophage. There is nothing in the art to suggest that adding phage to a sample is equivalent to adding a sample to phage; and, in fact, those skilled in the art generally know that the order of subprocesses in a process usually is of importance. Therefore, claims 4, 5, 7, 37 – 39, 84, and 85 are patentable

Claim 34 has been rejected under 35 USC 103(a) as being unpatentable over Rees et al. as applied to claims 1 – 3, 6, 14, 15, 18 – 23, 32, and 96 above, and further in view of Ulitzur et al. (EP 0168933, hereinafter "Ulitzur et al."), and in view of Bittner et al. (EP 0439354, hereinafter "Bittner et al."). This rejection is respectfully traversed. Claim 34 depends on claim 1, which is patentable, and is at least patentable for that reason.

Claims 1 – 3, 6, 7, 14, 15, and 96 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of Madonna et al. (US Patent No. 7,166,425, hereinafter "Madonna et al."). Claim 96 is withdrawn. A Terminal Disclaimer with regard to Madonna et al. is enclosed.

Claims 18 – 23 and 32 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of Madonna et al. in view of Rees et al. This rejection is respectfully traversed, since Rees et al. does not teach dissociating the progeny phage.

Claims 4, 5, 37 – 39, and 85 have been rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of Madonna et al. in view of Rittenburg et al. This rejection is respectfully traversed for the reasons given above with respect to the previous rejection over Rittenburg et al.

Claims 1 – 3, 7, 14, 15, 37 – 39, 84, 85, and 96 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 – 6, and 8 – 10 of Gaisford et al. (copending US Application No. 11/698,673, hereinafter "Gaisford et al."). This rejection is respectfully traversed. Claims 1, 2, 4 – 6, and 8 – 10 of Gaisford et al. include the limitation of waiting a predetermined time period such that, if the target microorganism is present in the sample at or above a threshold concentration, a marker will be amplified in the sample. Such a limitation is not in any of claims 1 – 3, 7, 14, 15, 37 – 39, 84 and 85 of the present application, and, in fact, is nowhere disclosed or suggested in the present application. Thus, there cannot be double patenting.

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In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. A Terminal Disclaimer and a one-month Petition For Extension Of Time, as well as the appropriate fees, are attached to this paper. Applicants believe no additional fee is due with this response. However, if any additional fee is due, please charge our Deposit Account No. 50-1848, under Order No. 022116.0102PTUS from which the undersigned is authorized to draw.

Respectfully submitted,
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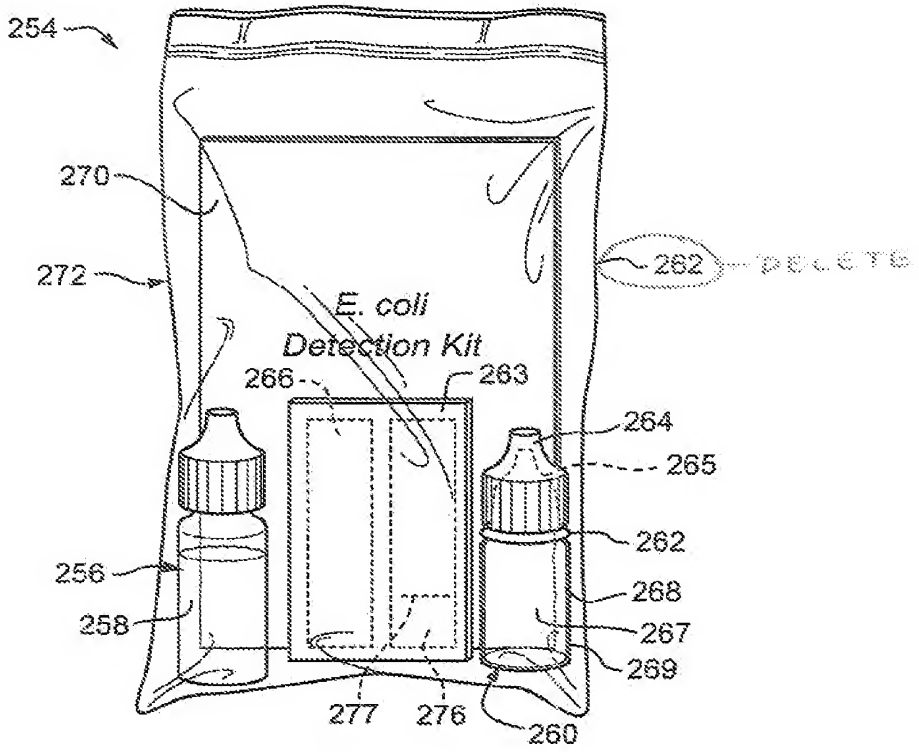
254
270
272
262
DELETE
E. coli
Detection Kit
266
263
264
265
262
256
268
258
267
269
277
276
260

FIG. 19

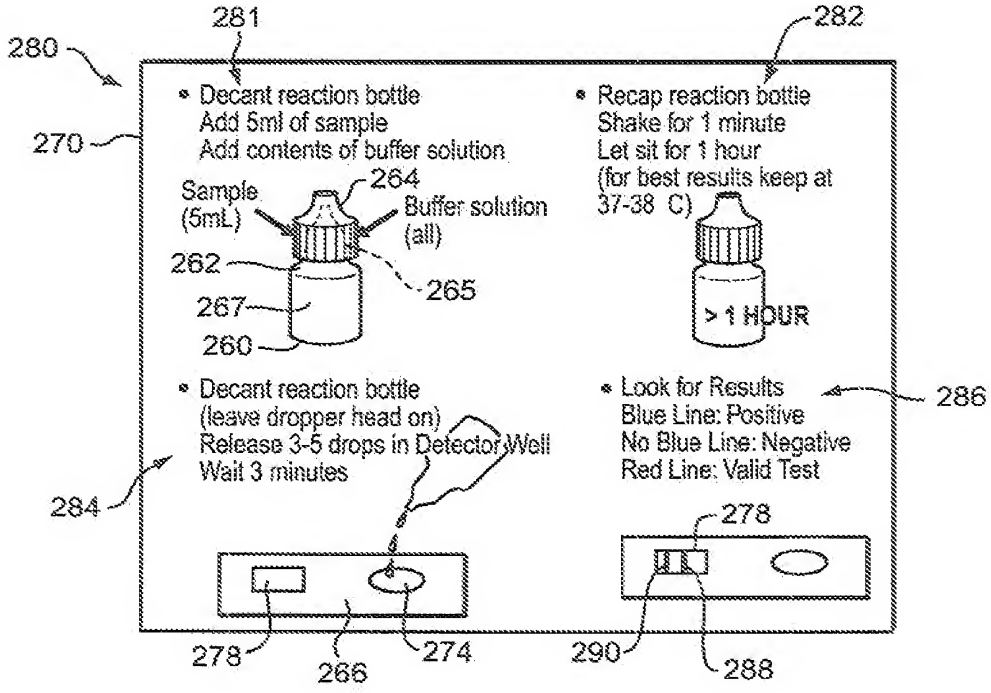
281
282
280
270
• Decant reaction bottle
Add 5ml of sample
Add contents of buffer solution
Sample
(5mL)
264
Buffer solution
(all)
262
265
267
260
• Recap reaction bottle
Shake for 1 minute
Let sit for 1 hour
(for best results keep at
37-38 C)
> 1 HOUR
• Decant reaction bottle
(leave dropper head on)
Release 3-5 drops in Detector Well
Wait 3 minutes
• Look for Results
Blue Line: Positive
No Blue Line: Negative
Red Line: Valid Test
286
284
278
278
266
274
290
288

FIG. 20

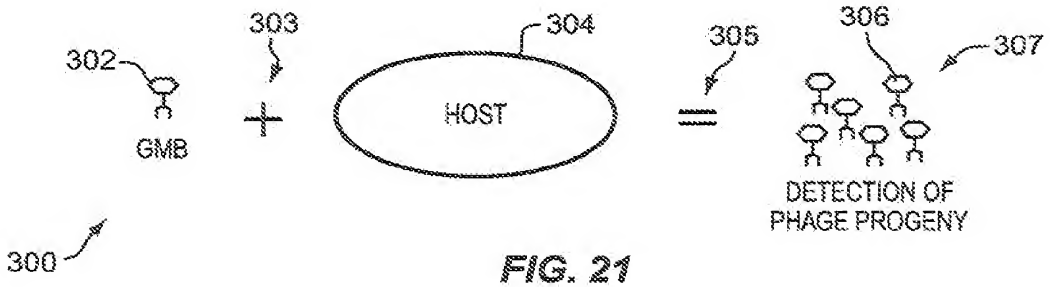

FIG. 21

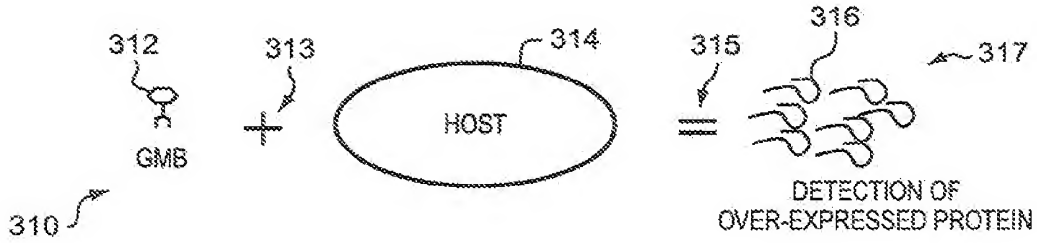

FIG. 22

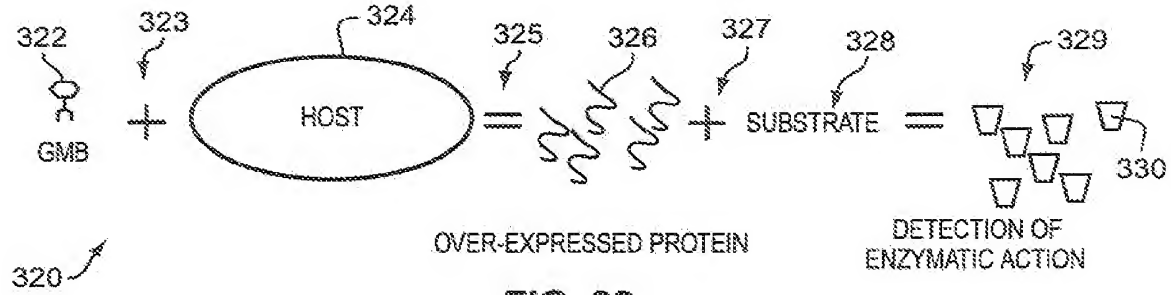

FIG. 23

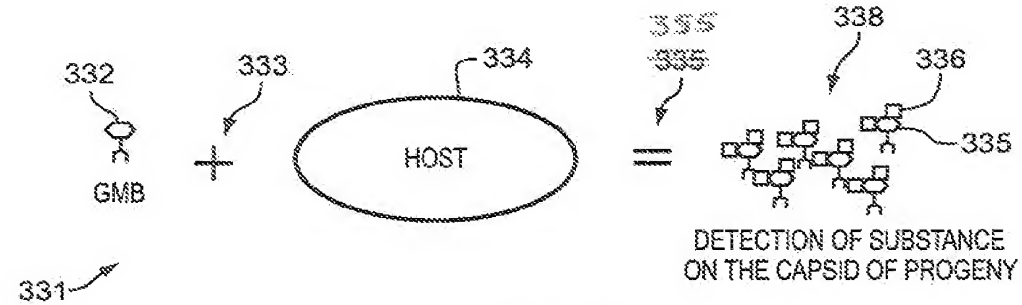

FIG. 24